***In re FibroGen, Inc. Securities Litigation*, No. 3:21-cv-02623-EMC (N.D. Cal)**

APPENDIX

Lead Plaintiffs' Chart Summarizing Allegedly False/Misleading Statement(s) and Omission(s)*
Pursuant to Court's Standing Order

** Plaintiffs respectfully refer the Court to the Consolidated Class Action Complaint, dated October 29, 2021, for a full recitation of their complete allegations. For ease of reference, Plaintiffs have presented Defendants' false and misleading statements according to each occasion, while listing each statement made during such occasion, and have alternated the highlighting for those occasions between gray and green.*

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Defendants False and Misleading Statements and Omissions	Reasons Why Defendants' Statements Were False and Misleading When Made	Facts Giving Rise to a Strong, Cogent and Compelling Inference of Defendants' Scienter
1-4	142-144	**Speaker(s)**: FibroGen, Neff (CEO), Yu (CMO) **Date**: December 20, 2018 **Occasion**: FibroGen Press Release announcing "Positive Topline Results from Three Global Phase 3 Trials of Roxadustat"	1. Defendant Yu: Roxadustat "***achieved superiority in efficacy not only against placebo but also over [Epogen] in our studies***," and "***[t]hese results support [R]oxadustat's potential to bring clinical benefit over current standard of care***." 2. Former CEO Neff: "[t]his is the first well-controlled CKD anemia program that has shown ***improved efficacy in incident and stable dialysis patients relative to [Epogen] standard of care therapy***." 3. Press Release: noted certain specific efficacy results, such as that "***in the pre-specified secondary efficacy analysis, Roxadustat-treated patients had a 33% reduction in the risk of blood transfusion compared to [Epogen]***." 4. Press Release: "***The preliminary safety analyses of each of these three individual studies show an overall safety profile consistent with the results observed in prior***	These statements were materially false and misleading and omitted material facts because the Phase 3 trials of Roxadustat did not show "superiority" or "improve[ment]" in efficacy over placebo or Epogen. To the contrary, the purportedly positive Roxadustat efficacy and safety data Defendants touted was based on Defendants' own improper *post hoc* manipulations of the data to make the drug look significantly better and safer than it was, and not on any prespecified analyses required by the FDA. In reality, Roxadustat's safety signals were so alarming that it was more dangerous than placebo and decidedly *inferior to* Epogen—rendering Roxadustat too dangerous to be approved *at all*. Thus, there was in fact no proof of *any* efficacy for Roxadustat because there were far too many serious safety signals for the drug to warrant approval for any patient population, regardless of any "Black Box" warning. With respect to the purported "reduction in the risk of blood transfusion compared to" Epogen, the FDA AdCom expressly determined on July 15, 2021 that this	**Defendants' *Post Hoc* Admissions** As Defendants *admitted* on April 6, 2021, Defendants had manipulated ***each and every one of nine key analyses*** of Roxadustat's clinical trial data by making blatantly improper "*post hoc* changes" to that data in order to make the drug appear significantly better and safer than it really was. In reality, Roxadustat's undisclosed, true data demonstrated that it was alarmingly ***inferior*** to Epogen and placebo due to severe safety issues, including increased deaths, that doomed the drug's chances for FDA approval. In FibroGen's own words, "based on [the undisclosed, true FDA prespecified] analyses ***we cannot conclude that Roxadustat reduces the risk of (or is superior to) … [Epogen]***." ¶¶81, 237. **Analysts Excoriated Defendants** Analysts uniformly excoriated management for their fraudulent data manipulations, emphasizing that the "meaningfully worse" data represented a "material change" in Roxadustat's safety profile, and that

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			Roxadustat studies. The adverse events reported are consistent with those expected in these study populations with similar background diseases."	claim was inconclusive *at best*, and likely nonexistent if the dose of Roxadustat was lowered to address the massive safety issues that prevented its approval. Moreover, Defendants knew that Roxadustat's safety signals—rather than being "consistent" with prior trials or "expect[ed]" in the study population—were in fact so numerous and "very concern[ing]" under the actual, undisclosed prespecified analyses required by the FDA, that the FDA AdCom would vote not to approve the drug at all. *See* ¶146.	it was "unclear" how Defendants only then purportedly learned of the changes. For example, Jefferies noted the "***key takeaway***" from Defendants' admissions was that the drug was "***no longer 'statistically superior'" to Epogen***, representing a "***material change***" to the drug's safety profile." H.C. Wainwright highlighted that the "***new dataset is weaker***"; "***the prior conclusion of [] superiority. . . is no longer supported by the new analysis***"; and it was "***unclear why the company only 'became aware' of this issue at this point in time***." Raymond James stated the new data was "***meaningfully worse*** than what was presented in the past," and William Blair noted that Defendants' admission "will negatively affect management's credibility." ¶¶89-93, 99; 238-39. **Medical Journals Rebuke the "Staggering Admissions"** In striking commentary, prominent medical publications also explicitly highlighted the intentional nature of Defendants' "***data doctoring***." For example, among many other rebukes, STAT+ emphasized that Defendants had been "***touting false heart safety data … for at least two years—a shocking revelation***," and concluded that "FibroGen cheated" by committing "the worst case of data manipulation in years." Evaluate Vantage noted that Defendants' explanation for the

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					"staggering admission" "***stretches the bounds of credibility***." And *FiercePharma* confirmed the intentional nature of Defendants' changes, noting that "***[t]he fact that all nine analyses*** [] looked less favorable [] after the change ***raises the suspicion that [] FibroGen carefully selected the new criteria to make Roxa's profile look better***." ¶¶94-95, 240. **Nephrologists Confirmed the Data Manipulations "Could [Not] Happen Accidentally"** Prominent nephrologists, including those with personal knowledge of the Roxadustat trials, likewise put the blame for the manipulations squarely on FibroGen management. For example, Dr. Coyne, a university professor and nephrologist who personally worked as a site investigator for the Roxadustat trials, emphasized that "[t]his deeply damages the reputation of FibroGen going forward. ***I feel very misled, and I don't think there is any excuse for this. I don't know how this could happen accidentally***." Dr. Porges, a prominent Wall Street biotech analyst, called Defendants' admission "***nothing less than stunning***" given that "[t]he re-statement reduced the benefit from [Roxadustat] vs controls ***in every case***, [and] ***erased the appearance of superiority over ESAs in incident dialysis patients***." ¶¶96-100, 241.

					Roxadustat's Significance Roxadustat was indisputably FibroGen's single most important drug and core operation during the Class Period. Indeed, analysts specifically noted that the drug ***accounted for 85-90% of FibroGen's market value***, and if the drug received FDA approval, its potential $3.5 billion market ***dwarfed*** FibroGen's $176 million in revenue for all of 2020 ***by 20 times***. ¶¶42, 246. **Defendants' Repeated Assurances** Defendants repeatedly assured investors about the "superior" efficacy and safety of Roxadustat literally dozens of times throughout the Class Period. When investors specifically questioned Defendants about the adequacy and accuracy of the drug's data, Defendants aggressively denied any issues whatsoever with that data. The fact that Defendants spoke so often and in such detail about the Roxadustat data makes clear that the data was critically important to them, and that they had fully analyzed that data and were intimately familiar with all of the clinical trial results. ¶¶142-235, 247-248. **Scope and Duration of the Fraud** Defendants' fraud lasted ***over two years***, which analysts repeatedly emphasized in directly implicating FibroGen management for the data manipulations. The longstanding nature of Defendants' fraudulent misrepresentations—and the degree to which those representations sharply conflicted with the actual

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					Roxadustat data Defendants had in hand but that they never fully revealed to investors—directly supports a strong inference of scienter. ¶¶247, 249, 257. **CWs Confirm Defendants' Complicity in the Fraud** Former employees of FibroGen's partner, AstraZeneca, confirmed that Defendants had first-hand knowledge, and control, of the Roxadustat data. For example, these CWs stated that during the Class Period, "***FibroGen was in control of the [Roxadustat] data and when the data was released***," and FibroGen's most senior management—including Neff and Defendant CMO Yu—were "***all over every bit of [the Roxadustat data]***"; Defendants "***played fast and loose***" with the drug's data, with "***investor confidence [being] the main game***"; and that Defendants manipulated the drug in a way that "***chang[ed] everything***" about "***[t]he relative significance of its efficacy in light of its safety***." These CWs further recalled that by the fall of 2020, Defendants knew that there were significant issues with that data and that the FDA might not approve the drug, at the same time Defendants were publicly representing the opposite. ¶¶121-127, 250-252. **Defendants Had Financial Motive** Neff and the Individual Defendants engaged in substantial and

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					coordinated insider selling during the Class Period of ***$42 million***. Significantly, Neff alone sold $32 million of that amount, and he received lucrative compensation and bonuses in 2018 totaling $9.2 million, which significantly increased to ***$11.4 million in 2019***, the year FibroGen submitted the NDA. Yu received $4.5 million in total compensation and bonuses in 2018 and received over ***$10 million*** in awards directly tied to "the completion of the Roxadustat MACE safety analysis" and her work on the NDA. Yu also engaged in significant insider sales during the Class Period, reaping over $2 million in profits. FibroGen itself stood to receive large milestone payments from AstraZeneca, which comprised a significant portion of FibroGen's revenue during the Class Period. ¶¶134-39, 253-54. **<u>FibroGen's Milestone Payments</u>** Defendants stood to receive highly substantial milestone payments from FibroGen's partner AstraZeneca, totaling $1.2 billion for developmental, regulatory and commercial milestones if Roxadustat was approved by the FDA for commercially viable patient populations. ¶¶38, 43, 66, 256. **<u>Defendant Yu's Resignation</u>** Defendants announced the abrupt and suspiciously timed departure of Defendant Yu on November 27,

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					2020, less than one month prior to the PDUFA date of December 20, 2020 and at the exact same time Plaintiffs' CWs stated the FDA was informing FibroGen that, at the very least, Roxadustat would require a Black Box warning due to numerous safety issues the FDA had uncovered. As a May 17, 2021 *SeekingAlpha* article noted, "[n]o reason was given" for Yu's abrupt departure, which was highly suspicious considering that Yu was the lead author of the specific scientific paper regarding the Roxadustat data that later had to be retracted due to Defendants' fraud. ¶¶100, 258.
5-7	145-146	**Speaker(s)**: FibroGen, Neff (CEO), Yu (CMO) **Date**: February 27, 2019 **Occasion**: 4Q and FY 2018 Earnings Call	5. Neff: All of the Phase 3 Roxadustat studies "***have positive top line results***" and "***support our NDA [to the FDA]***" …"***based on our review of the data…there is a strong conviction to move ahead to file the NDA…this year***." 6. Yu: "***superiority [to Epogen] was demonstrated in all 3 dialysis studies***," and ***of "much clinical importance"*** was the fact that ***"Roxadustat was [] shown to have a lower [red blood cell] transfusion risk than ESA***," which Yu emphasized was a "***big deal***" and "***of great significance to CKD patients***." 7. Yu: With respect to the preliminary safety data from the trials, Yu reiterated that the	*See* reasons for falsity provided in connection with Statements 1-4.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4.

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			"***[r]esults in individual studies are consistent with what one would expect in the study patient population,***" and stated that FibroGen was "***encouraged by the robust efficacy results, the preliminary safety data in individual Phase 3 studies and the ongoing pool efficacy and safety analyses***."		
8-13	147-152	**Speaker(s)**: FibroGen, Neff (CEO), Yu (CMO) **Date**: May 9, 2019 **Occasion**: Press Release announcing "Positive Topline Results From Pooled Safety Analyses of Roxadustat Global Phase 3 Program" (the "May 2019 Press Release")	8. Press Release: FibroGen claimed that: (i) there was "***no clinically meaningful difference in [MACE] risk***" between the two treatment arms for DD and NDD patients; and that (ii) ***Roxadustat had achieved "[s]uperiority in time to first MACE+ versus [Epogen] in incident dialysis patients"*** and that there was "***a trend toward reduced [MACE] risk for patients on [R]oxadustat***" compared to Epogen. 9. Press Release: FibroGen stated that the "ITT [intention-to-treat]" method was "among the several statistical methods that we will discuss with the FDA," and that ***"[i]n these analyses, Roxadustat was comparable based on a commonly applied non-inferiority margin of 1.3***." 10. Yu: "***[w]e are particularly excited about the results indicating a reduction of risk of MACE+ events in incident dialysis patients.***"	In addition to the reasons for falsity set forth above, Defendants' statements in the May 2019 Press Release are also false and misleading and omitted material facts for the following additional reasons. *First*, Defendants' claim that there was no "clinically meaningful difference in risk of MACE between Roxadustat" and placebo in NDD patients—or between Roxadustat and Epogen in DD patients—was false. To the contrary, Defendants improperly manipulated the Roxadustat safety data *post hoc* in order to make the drug appear significantly better and safer than it was. As the FDA would reveal at the end of the Class Period, under the true, undisclosed prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "serious" that the drug was more dangerous than placebo and decidedly *inferior to* and caused *more deaths than* Epogen, rendering Roxadustat too dangerous to be approved *at all*. *Second,* as Defendants were well aware, under the undisclosed prespecified analyses, there was no statistically significant "superiority" of Roxadustat	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4. In addition, with respect to Defendants' statements that the FDA would be evaluating the Roxadustat safety data against the "commonly applied" non-inferiority margin of 1.3, the FDA stated that it had directly told FibroGen during its pre-NDA meetings with the Company that it did ***"not agree with [FibroGen's] proposed [non-inferiority] margin of 1.3"*** because "it was defined [by FibroGen] after the results of the study were known." The FDA further informed FibroGen during those meetings that the agency "had a goal of ***1.25***"—*i.e.*, a significantly lower non-inferiority margin than 1.3—a fact Defendants never disclosed to investors. ¶¶55, 110.

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			11. Neff: "[w]e are very pleased with what we believe are important positive results of MACE and MACE+ analyses in the dialysis-dependent, incident dialysis, and non-dialysis dependent CKD patients, supporting the safety of Roxadustat in CKD patients . . . ***these positive safety data give us confidence as we progress in preparation for the U.S NDA***..." 12. Neff: In the press release, Neff touted certain Roxadustat efficacy results, namely a "***reduction of transfusion, and the encouraging results from the pooled analyses of Quality of Life***." 13. Yu: touted the "additional potential clinical benefits of Roxadustat," including a purported "***improvement of quality of life in NDD-CKD patients***," which the press release claimed was "statistically significant" in NDD patients.	over Epogen for the MACE+ endpoint in the crucial incident dialysis population, nor was there "a trend toward reduced [MACE] risk for patients on Roxadustat." To the contrary, FibroGen could only claim this result after manipulating the data *post hoc* to make the drug seem much safer than it was. Indeed, based on the *actual* prespecified analyses required by the FDA, Defendants *admitted* in the April 6, 2021 press release that they "***[could not] conclude that Roxadustat reduces the risk of (or is superior to) . . . MACE and MACE+ in incident dialysis compared to [Epogen]***." *Third*, rather than there being any "statistically significant improvements" in quality of life data for NDD patients taking Roxadustat, the exact opposite was true—as the FDA AdCom would expressly determine, based on the drug's true, undisclosed analyses, there was in fact "***a surprising lack of improvement in quality of life***" in NDD patients taking Roxadustat. *Fourth*, Defendants' assertion that under the ITT analysis—which Defendants claimed was one of several prespecified analyses discussed with the FDA—Roxadustat had achieved non-inferiority because its hazard ratio was below the "commonly applied" 1.3 threshold was also false. Indeed, as the FDA would reveal during the July 15, 2021 AdCom, in FibroGen's private negotiations with the FDA about the prespecified non-inferiority margin, the FDA in fact ***did "not agree with [FibroGen's] proposed***	

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				[non-inferiority] margin of 1.3" because "it was defined [by FibroGen] after the results of the study were known"—in other words, FibroGen had defined the 1.3 margin for itself, *post hoc* and after the data were fully unblinded, with no agreement from the FDA. Moreover, the FDA revealed that, during its pre-NDA meetings with FibroGen, the FDA in fact "***had a goal of 1.25***, and ***that's what we discussed during meetings[,] [s]o that's why there was not an agreement on 1.3***."	
14-21	153-161	**Speaker(s)**: FibroGen, Neff (CEO), Yu (CMO) **Date**: May 9, 2019 **Occasion**: Q1 2019 Earnings Call	14. Neff: In response to analyst questions about the meaning of the "clinically meaningful" statement, Neff stated that it "***mean[t] that [Roxadustat] met the safety standards that people were looking for and that's why people are moving forward"*** and ***"the message there is we're trending favorably***." 15. Neff and Yu: Defendants Neff and Yu also further emphasized the purported numerical advantage in MACE+ of Roxadustat versus Epogen, with Defendant Neff asserting that in "***[e]very one of [the MACE+ categories]***"—which Defendants explained encompassed MACE all events—"***we have a numeric advantage over ESA… Fewer events in Roxa versus ESA in deaths. Fewer events in Roxa versus ESA in myocardial infarction. Fewer strokes in***	In addition to the reasons for falsity set forth above, Defendants' statements during the Q1 2019 Earnings Call were materially false and misleading and omitted material facts for the following additional reasons. *First*, Defendants' claim that there was no "clinically meaningful difference in risk of MACE between Roxadustat" and placebo in NDD patients—or between Roxadustat and Epogen in DD patients—was false. To the contrary, Defendants improperly manipulated the Roxadustat safety data *post hoc* in order to make the drug appear significantly better and safer than it was. As the FDA would reveal at the end of the Class Period, under the true, undisclosed prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "concerning" that the drug was more dangerous than placebo and decidedly *inferior to* Epogen, rendering Roxadustat too dangerous to be approved *at all*. *Second,* as Defendants were well aware, under the undisclosed prespecified	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4 and 8-13. Moreover, Defendants' strong, affirmative and false responses to analysts' direct questions about whether the data FibroGen was presenting was sanctioned by the FDA is highly probative of scienter. ¶248.

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			Roxa than ESA. Fewer unstable angina hospitalizations. Fewer congestive heart failures resulting in hospitalizations." Defendant Yu agreed with these representations. 16. Yu: For NDD patients, Yu stated that "***because our drug is so efficacious and so well tolerated, patients really like staying on our drug***," and that, under the purportedly "conservative" ITT analysis, "***the fact that . . . we are able to show non-inferiority to placebo under such conditions***"—which Yu stressed was "***the gold standard for safety***"—"***really illustrates the strength of our drug's safety***." 17. Yu: For incident dialysis patients, Yu stated: "***[F]or us to state that we are superior in time to MACE+ analysis in incident dialysis, what I mean is the upper bound of the 95% confidence interval is less than 1. And [] when you compare the hazard between Roxadustat to that of [Epogen], we have a very significant p value***." 18. Yu: In response to a direct analyst question seeking "reassurance" regarding the "number of deaths, MIs and strokes" (*i.e.*, MACE events) in the overall DD patient population as opposed to the incident dialysis subpopulation,	analyses, there was no statistically significant "superiority" of Roxadustat over Epogen for the MACE+ endpoint in the crucial incident dialysis population, nor was there "a trend toward reduced [MACE] risk for patients on Roxadustat." To the contrary, FibroGen could only claim this result after manipulating the data *post hoc* to make the drug seem much safer than it was. Indeed, based on the *actual* prespecified analyses required by the FDA, Defendants *admitted* in the April 6, 2021 press release that they "***[could not] conclude that Roxadustat reduces the risk of (or is superior to) . . . MACE and MACE+ in incident dialysis compared to [Epogen]***." *Third*, rather than there being any "statistically significant improvements" in quality of life data for NDD patients taking Roxadustat, the exact opposite was true—as the FDA AdCom would expressly determine, based on the drug's true, undisclosed analyses, there was in fact "***a surprising lack of improvement in quality of life***" in NDD patients taking Roxadustat. *Fourth*, Defendants' assertion that under the ITT analysis—which Defendants claimed was one of several prespecified analyses discussed with the FDA—Roxadustat had achieved non-inferiority because its hazard ratio was below the "commonly applied" 1.3 threshold was also false. Indeed, as the FDA would reveal during the July 15, 2021 AdCom, in FibroGen's private negotiations with the FDA about the prespecified non-	

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			Yu replied, "***we are quite comfortable with the safety result when looking at MACE and MACE+***" and verified that the rates of events in each of the MACE and MACE+ categories were at least comparable as between Roxadustat and Epogen. Specifically, Yu stated: "***[W]hen we tested time to—for example, MACE+ and MACE, Roxadustat was at least non-inferior to [Epogen] even in the conversion stable dialysis patients***." 19. Neff: in response to analyst questions, Neff stated that the Company felt the ITT results were what "***describe[ed] the situation most effectively***," and ***asserted that an upper bound on the hazard ratio of 1.3 under the ITT analysis was the "safety evaluation standard the FDA usually asks for***." 20. Yu: in response to an analyst question regarding whether Roxadustat had achieved statistical non-inferiority on the FDA's MACE endpoint, Yu stated: ***"[W]e are using the conventional standards of noninferiority, which is widely published for assessment of CKD anemia and have previously been used by [the FDA] for assessment of cardiovascular safety*** in similar	inferiority margin, the FDA in fact ***did "not agree with [FibroGen's] proposed [non-inferiority] margin of 1.3" because "it was defined [by FibroGen] after the results of the study were known"***—in other words, FibroGen had defined the 1.3 margin for itself, *post hoc* and after the data were fully unblinded, with no agreement from the FDA. Moreover, the FDA revealed that, during its pre-NDA meetings with FibroGen, the FDA in fact "***had a goal of 1.25***, and ***that's what we discussed during meetings[,] [s]o that's why there was not an agreement on 1.3***." *Fifth*, with respect to Defendant Yu's response to analyst questions regarding whether FibroGen believed it would avoid the dreaded "Black Box" warning from the FDA, Defendants' statement that FibroGen was "comfortable with safety" and believed that there would be no need for a "Black Box" warning was not based on Defendants' discussions with the FDA about what it wanted to see, but rather on Defendants' *post hoc* manipulations of the Roxadustat data in order to make the drug appear significantly safer than it was. Indeed, as the FDA would ultimately reveal, Defendants knew that the under the actual prespecified analyses agreed upon with the FDA, the Roxadustat safety data showed that the drug had far too numerous serious safety issues to be approved at all, for any patient population, and regardless of any "Black Box" warning. In fact, CW 3, the former Global Vice President of Anemia Therapeutics at AstraZeneca who was	

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			types of composite endpoints . . .***that standard has been 1.3 for upper bound of 95% confidence interval. If we use that standard, the answer is yes, we have achieved non-inferiority."*** 21. Yu: When directly asked by an analyst whether FibroGen believed it would avoid the dreaded "Black Box" warning on Roxadustat's label based on the MACE safety data, Defendant Yu responded: "***[B]ased on what we have seen, we are pretty comfortable with safety. The adjudicated composite safety endpoint was something that we have discussed with the FDA***."	directly involved in labeling conversations with FibroGen and the FDA, stated that the FDA explicitly determined that, at the very least, Roxadustat's alarming safety issues would undoubtedly require a "Black Box" warning—a conclusion Defendants knew the FDA would inevitably reach based on Roxadustat's safety results under the real prespecified analyses that Defendants had concealed throughout the Class Period.	
22	136-138, 162, 149-151	**Speaker(s)**: FibroGen, Neff (CEO), Cotroneo (CFO) **Date**: May 9, 2019 **Occasion**: Q1 2019 Form 10-Q	22. FibroGen, Neff and Cotroneo: FibroGen filed with the SEC FibroGen's Form 10-Q for Q1 2019, in which it reiterated the topline MACE safety results set forth in the May 2019 Press Release. Specifically, for DD patients, the 10-Q again stated that "[f]or the U.S., where the focus will be on MACE, based on the collective results of the various MACE analyses, we believe there is ***no clinically meaningful difference in MACE risks between roxadustat and epoetin alfa***." For incident dialysis, "there was a trend toward ***reduced risk of***	*See* reasons for falsity provided in connection with Statements 1-21.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13 and 14-21. In addition, Defendant Cotroneo also made significant insider sales of approximately $7 million that were suspicious in both timing and amount, and which represented nearly 40% of his total vested securities as of April 1, 2018, per FibroGen's 2018 Proxy Statement.

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			MACE for patients on roxadustat, compared to epoetin alfa." For NDD, "[f]or the U.S., where the focus will be on MACE, based on the collective results of the various MACE analyses, we believe there is ***no clinically meaningful difference in MACE safety between roxadustat and placebo in this same non-dialysis population***."		
23-24	163-166	**Speaker(s)**: FibroGen, Neff (CEO), Yu (CMO) **Date**: June 12, 2019 **Occasion**: Goldman Sachs 40th Annual Global Healthcare Conference	23. Yu: Yu once again touted Roxadustat's Phase 3 trial results and the "***compelling evidence confirming [R]oxadustat's cardiovascular safety to support our regulatory filings***." Yu reiterated that "***our MACE results in dialysis and in non-dialysis also support the conclusion of no increased cardiovascular safety risk***." Yu also "emphasize[d] ***[the] MACE+ superiority in [the] incident dialysis pool,***" and touted certain "efficacy benefits" of Roxadustat, including ***"transfusion reduction" and "improvement in quality of life."*** 24. Neff: Neff similarly stated that the Company was "in a place now ***where we have safety data and efficacy data that's superior to [Epogen] in a U.S.***	In addition to the reasons for falsity set forth above, Defendants' statements during the Goldman Sachs conference were materially false and misleading and omitted material facts for the following additional reasons. *First*, Defendants' claims of "compelling evidence confirming Roxadustat's cardiovascular safety"; that they had "safety and efficacy data that's superior to Epogen"; and that Roxadustat was "differentiated" because it was "as safe as placebo" were plainly false, as Defendants had secretly engaged in blatantly improper *post hoc* manipulations to the Roxadustat clinical trial data which were designed to make the drug appear significantly better and safer than it was. As Defendants would *admit* in the April 6, 2021 press release, under the actual prespecified analyses and once the *post hoc* changes Defendants had made were corrected, there was no "superiority" of Roxadustat over Epogen in the crucial incident dialysis population.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13 and 14-21.

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Defendants False and Misleading Statements and Omissions	Reasons Why Defendants' Statements Were False and Misleading When Made	Facts Giving Rise to a Strong, Cogent and Compelling Inference of Defendants' Scienter
			setting," and further added: "In the U.S., there are a couple of factors related to ***how we've differentiated ourselves*** and I think in one respect doing the work to do [a] placebo study in CKD ***and show that we are as safe as the placebo control arm is a very exciting place to be…*** in an incident dialysis setting . . . ***we've had outstanding results in this area.*** We think it's the most fair comparison of [Epogen] to Roxa. ***We think it opens the door to Roxa being recommended as a first medicine . . . [I]t looks very, very promising at this point."*** Neff also asserted that, based on the MACE data the Company had seen, Roxadustat "shouldn't have a 'Black Box'" warning: "[A] key goal in the U.S. was—with CKD population, a placebo study was to show non-inferior to placebo, to show that there isn't any incremental risk measure so that it ***opens the door to the logic [that Roxadustat] shouldn't have a 'Black Box' for placebo. Therefore, Roxa should not have a 'Black Box'*** and go from there in dealing with dialysis. ***And it's turned out as we hoped for."***	*Second*, as the FDA would reveal at the end of the Class Period, under the FDA's prespecified sensitivity analyses which Defendants never disclosed during the Class Period, Roxadustat's safety signals were so alarming and "very concern[ing]" that the drug was in truth much more dangerous than placebo and decidedly *inferior to* Epogen, rendering Roxadustat too dangerous to be approved *at all*, for any patient population. Accordingly, Defendants' statement that Roxadustat's safety data would not warrant any "Black Box" warning was also materially false and misleading—as Defendants knew, their own undisclosed analyses showed that Roxadustat was *less safe* than Epogen, which already had the "Black Box" warning. *Third*, as Defendants knew, and as the FDA would reveal at the end of the Class Period, there was in fact no "statistically significant improvements" in quality-of-life measures for NDD patients taking Roxadustat nor was there any reduction in blood transfusions—to the contrary, the FDA saw no signs of any such improvements at all.	

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25-27	167-168, 170	**Speaker(s)**: FibroGen, Neff (CEO), Yu (CMO) **Date**: August 8, 2019 **Occasion**: Q2 2019 Earnings Call	25. Neff: Neff announced that Company had "reached an agreement with the [FDA] on the content of the NDA including the cardiovascular safety analysis." 26. Yu: Yu then emphasized Roxadustat's MACE safety results, stating that "***Phase 3 results confirmed the cardiovascular safety of [R]oxadustat***." Yu further touted FibroGen's interactions with the FDA, highlighting that the Company had a "very good pre-NDA meeting with the FDA on [R]oxadustat" where FibroGen and the FDA reached an agreement "on our proposed pooled MACE analysis." Yu claimed that FibroGen was "***very pleased with the agreement [with the FDA] on the primary safety analysis of our primary cardiovascular safety endpoint in NDD***." 27. Yu: In response to an analyst question about whether FibroGen had "confidence around the statistics" in light of the agreement reached with the FDA, Yu expressed FibroGen's "***confidence on non-inferiority of MACE***," stating that the Company's "***level of confidence is very high***, and we do believe .	In addition to the reasons for falsity set forth above, Defendants' statements in the Q2 2019 Earnings Call were materially false and misleading, and omitted material facts when made, for the following additional reasons. Specifically, the Phase 3 clinical trials did not "confirm[] the cardiovascular safety of Roxadustat," nor did Defendants have "very high" confidence in Roxadustat's MACE non-inferiority based on the agreement FibroGen had reached with the FDA on the statistical analyses. To the contrary, Defendants' claims of Roxadustat's "cardiovascular safety" were the result of Defendants' own *post hoc* manipulations of the Roxadustat data that were designed to make the drug appear significantly safer than it was. As the FDA would reveal at the end of the Class Period, under the true, undisclosed prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "very concern[ing]" that the drug was much more dangerous than placebo and decidedly *inferior to* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13 and 14-21.

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Defendants False and Misleading Statements and Omissions	Reasons Why Defendants' Statements Were False and Misleading When Made	Facts Giving Rise to a Strong, Cogent and Compelling Inference of Defendants' Scienter
			. . that ***our Phase 3 results confirm cardiovascular safety of [R]oxadustat in the CKD population in both dialysis and non-dialysis***." Yu also further emphasized that "***on the safety side– the ability to demonstrate a drug is as safe as placebo which is a very high bar,*** because placebo is considered to give the drug an opportunity to show how safe it is based on its own merit."		
28	169-170	**Speaker(s)**: FibroGen, Neff (CEO), Cotroneo (CFO) **Date**: August 8, 2019 **Occasion**: Form 10-Q for Q2 2019	28. Defendants: The 10-Q stated that the Company "***reached agreement on the content to be included in our NDA submission package for Roxadustat for treatment of anemia in CKD, including the cardiovascular safety analyses for both CKD-dialysis and CKD-non-dialysis.*** The agreement for non-dialysis is an approach to account for the differential dropout between roxadustat and placebo observed in our Phase 3 studies. ***We are confident we have sufficient data for FDA review of our NDA in both CKD dialysis and CKD non-dialysis*** and we are planning to submit the NDA in October of 2019."	*See* reasons for falsity provided in connection with Statements 25-27.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13 and 14-21.
29-32	171-175	**Speaker(s)**: FibroGen **Date**:	29. FibroGen: In the press release, which was also filed with the SEC on Form 8-K, FibroGen announced that (i)	In addition to the reasons for falsity set forth above, Defendants' statements in the ASN 2019 Press Release were materially false and misleading, and	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Defendants False and Misleading Statements and Omissions	Reasons Why Defendants' Statements Were False and Misleading When Made	Facts Giving Rise to a Strong, Cogent and Compelling Inference of Defendants' Scienter
		November 8, 2019 **Occasion**: Press release announcing "Positive Phase 3 Pooled Roxadustat Safety and Efficacy Results" that had been presented at ASN Kidney Week 2019 ("ASN 2019 Press Release")	***"Roxadustat cardiovascular safety [was] comparable to placebo in [NDD] patients" under MACE***; (ii) ***it "did not increase risk of MACE and reduced risk of MACE+ compared to [Epogen]" in DD patients***; and (iii) that it purportedly ***"reduced risk of MACE by 30% and MACE+ by 34% compared to [Epogen]" in the crucial incident dialysis population.*** 30. FibroGen: In the press release, FibroGen reported a MACE hazard ratio of 0.96 (95% confidence interval, 0.82 to an upper bound of 1.13) for DD patients; a MACE hazard ratio of 1.08 (95% confidence interval, 0.94 to an upper bound of 1.24) in NDD patients.; and a MACE hazard ratio of 0.70 (95% confidence interval, 0.51 to an upper bound of 0.96) in incident dialysis patients. 31. FibroGen: The press release proclaimed that, in total, "[t]he pooled safety analyses assessing Roxadustat . . . demonstrate a cardiovascular safety profile ***comparable with placebo in [NDD] patients,*** and ***comparable or in some cases better than that of [Epogen] in patients on dialysis."*** 32. FibroGen: The press release expressly clarified that for NDD patients**,** the results were based	omitted material facts when made, for the following additional reasons. *First,* as Defendants would *admit* in the April 6, 2021 press release, the statements Defendants made about the safety and efficacy results for Roxadustat—including the specific MACE hazard ratios and Defendants' claims that they had achieved "non-inferiority" compared to placebo and statistical superiority compared to Epogen in the crucial incident dialysis population—were materially false because Defendants had *post hoc* manipulated the data to make the drug appear significantly better and safer than it was. Thus, as Defendants would be forced to admit in the April 6, 2021 press release, rather than Roxadustat lowering the MACE risk in the crucial incident dialysis population by a statistically significant 30%, once the *post hoc* changes were corrected ***Defendants could not "conclude that Roxadustat reduces the risk of (or is superior to) MACE+ in [DD], and MACE and MACE+ in incident dialysis compared to [Epogen]" at all***. *Second*, as Defendants well knew, under the prespecified analyses Defendants had agreed upon with the FDA—and in particular the prespecified sensitivity analyses Defendants concealed from investors throughout the Class Period—Roxadustat's cardiovascular safety was not "comparable to placebo" in NDD patients, nor was it comparable to Epogen in DD patients. To the contrary, Roxadustat's safety signals were so	connection with Statements 1-4, 8-13 and 14-21.

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			on the ***"ITT analysis agreed with the FDA" and that the "[r]isks of MACE, MACE+, and all-cause mortality in Roxadustat patients were comparable to placebo in the ITT analyses based on a reference non-inferiority margin of 1.3."*** In the DD patient population, the release stated that ***"[r]isks of MACE and all-cause mortality in Roxadustat patients were not increased compared to those for patients receiving [Epogen] based on a reference non-inferiority margin of 1.3" and further claimed that "[r]isk of MACE+ was 14% lower in Roxadustat-treated patients than in those receiving [Epogen.]."*** For the crucial incident dialysis population, the release stated that the ***"[r]isk of MACE was 30% lower in Roxadustat patients than in epoetin alfa patients, and risk of MACE+ was 34% lower."***	alarming and "very concern[ing]" that the drug was in fact much more dangerous than placebo, and decidedly *inferior to* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population. *Third*, Defendants' claims that Roxadustat had achieved inferiority in the MACE endpoint by referencing the non-inferiority margin of 1.3 were also false. As set forth above, the FDA's goal for the Roxadustat trials was a non-inferiority margin of 1.25, not 1.3—and in fact, the FDA had expressly *rejected* FibroGen's proposal of the 1.3 non-inferiority margin because it had chosen that margin for itself *post hoc*, *after* the data had been fully unblinded. Moreover, under the FDA prespecified analyses that FibroGen *never disclosed*—and which were in fact disclosed ***by the FDA*** during the July 15, 2021 AdCom—Roxadustat's hazard ratio margins actually greatly *exceeded* 1.3, with the NDD margin reaching 1.70 under MACE and 1.82 under all-cause mortality, and the DD margin reaching 1.3 under MACE and 1.35 under all-cause mortality. These undisclosed analyses were highly material, as the FDA's AdCom meeting minutes and hearing transcript confirmed that they contributed significantly to the AdCom panel's overwhelming vote recommending against the approval of Roxadustat for any patient population.	
33-35	177-178,	**Speaker(s)**:	33. Schoeneck: Defendant Schoeneck, the Company's Interim CEO at the time	In addition to the reasons for falsity set forth above, Defendants' statements in the 3Q 2019 Earnings Call were	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in

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	182-183	FibroGen, Schoeneck (Int. CEO), Yu (CMO) **Date**: November 11, 2019 **Occasion**: 3Q 2019 Earnings Call	following former CEO Neff's passing, reaffirmed that Roxadustat's "***cardiovascular safety was comparable to placebo in [NDD] patients***"; "***in [DD] patients, roxa[] did not increase the risk of MACE and reduce[d] the risk of MACE+ compared to [Epogen]***"; and in "***incident dialysis patients, roxa[] reduced MACE by 30% and MACE+ by 34% compared to [Epogen]***," which was purportedly "unlike anything currently on the market in the U.S. or Europe." 34. Yu: Defendant Yu responded to questions about recent "investor concern about FDA agreements and FDA signoff," including a November 4, 2019 short report authored by short seller Plainview Capital LLC. Yu reassured investors that the Company had "a very productive dialogue with the FDA on the analysis of cardiovascular safety" and that, "***walking out of it, we felt that we had all the guidance from the FDA we needed to put together a winning submission***." Yu: When further pressed on whether Yu had any concern "about the hazard ratios and the upper bounds," ***Yu responded that she had "no concern about that" and that FibroGen was***	materially false and misleading, and omitted material facts when made, for the following additional reasons. *First,* as Defendants well knew, the detailed MACE safety results they had presented were not "based on the agreed upon analysis plan that we have made with the FDA," as the exact opposite was true. In reality, they were based on FibroGen's own *post hoc* analysis of the Roxadustat trial data conducted *after* the data was unblinded and manipulated to make the data appear significantly better than it was. Indeed, Defendants would admit on April 6, 2021 that the hazard ratios for each of the patient populations under the prespecified FDA analyses were in fact, in the words of market analysts, "***meaningfully worse***" in every patient population. Defendants therefore knew that they did not have what they needed for a "winning submission" to the FDA for Roxadustat. Moreover, under the FDA's actual prespecified analyses, Roxadustat's safety signals were so alarming and "serious" that the drug was in fact much more dangerous than placebo, and decidedly *inferior to* and caused *more deaths than* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population. *Second*, Defendants' claims that Roxadustat had achieved non-inferiority in the MACE endpoint by referencing the non-inferiority margin of 1.3 was also false. As set forth above, the FDA revealed during the AdCom that it had never agreed with FibroGen on a non-	connection with Statements 1-4, 8-13 and 14-21.

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			"very comfortable with our data where it is now." 35. Yu: On the call when Yu was asked again about whether the FDA had signed off on the analyses the Company had presented, Yu responded: So the answer to that question is that we had already talked with the FDA about [the] analytical plan, and we had made the agreement on the analysis plan. The results that we have presented in the high-impact clinical session at the ASN, and ***the numbers I had just presented, were based on the agreed upon analysis plan that we have made with the FDA*** . . . [W]e are confident that we do have what it takes for this drug to be favorably evaluated.	inferiority hazard ratio margin of 1.3—to the contrary, based on prior experience with ESAs, the FDA's goal was a non-inferiority margin of 1.25. Moreover, under the FDA prespecified sensitivity analyses that FibroGen ***never disclosed***—and which were in fact disclosed ***by the FDA*** during the July 15, 2021 AdCom—Roxadustat's hazard ratio margins were significantly worse and in fact greatly ***exceeded*** 1.25 *and* 1.3 in every key endpoint.	
36	179, 182-183	Speaker(s): FibroGen Date: November 14, 2019 Occasion: Email to Buyers Strike, the author of a November 12, 2019 short report	36. FibroGen: The short seller BuyersStrike published an email it received from FibroGen in response to its report. Iin the email, FibroGen asserted: "We do not agree with this report . . . ***The data presented at [ASN] reflect the analytical methods and study pools agreed upon with the FDA***."	*See* reasons for falsity provided in connection with Statements 33-35.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13 and 14-21.

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37-38	181-183	Speaker(s): FibroGen, Schoeneck (Int. CEO), Cotroneo (former CFO) Date: November 12, 2019 Occasion: Form 10-Q for Q3 2019	37. Defendants: The 10-Q presented how the ***"cardiovascular safety analysis reflects the pooling strategy and analytical approach we agreed on with the FDA***." 38. The 10-Q added that in FibroGen's "pre-NDA meeting, the ***FDA agreed that the ITT-analysis would be our primary cardiovascular safety analysis method for non-dialysis in the U.S***. as it uses on-treatment and post-treatment long term follow-up (until a common study end date) to account for the higher drop-out rate in the placebo arm. ***The figure below shows that in the 4,270 pooled non-dialysis patients (OLYMPUS, ANDES, and ALPS), the risk of MACE, MACE+, and all-cause mortality in Roxadustat patients were comparable to that in placebo patients based on a reference non-inferiority margin of 1.3."***	*See* reasons for falsity provided in connection with Statements 33-35.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13 and 14-21. In addition, Defendant Schoeneck received over $5.2 million in total compensation for his short role as interim CEO of FibroGen in 2019. Schoeneck also made substantial insider sales, yielding him approximately $500 thousand in proceeds during that short time. ¶¶137-138.
39-43	184-186	Speaker(s): FibroGen, Conterno (CEO) Date: February 25, 2020 Occasion: SVB Leerink	39. Conterno: At the conference, Defendant Conterno stated that "***the [Roxadustat] data that we have on cardiovascular safety is very compelling***." 40. Conterno: Defendant Conterno went on to say that "***when we look at the data, basically – we basically show to be comparable to placebo***" and that "***our data [is] extremely***	In addition to the reasons for falsity set forth above, Defendant Conterno's statements in the SVB Leerink Global Healthcare Conference were materially false and misleading, and omitted material facts when made, for the following additional reasons. *First*, Defendants' claims of "very compelling" cardiovascular safety data for Roxadustat, and that Roxadustat was "comparable to placebo," were plainly false because they were based on	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13 and 14-21.

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		Global Healthcare Conference	***clean … from my perspective when it comes to cardiovascular safety***." 41. Conterno: Conterno emphasized that "***we have a trial that, in my view, basically, shows safety against what I think is a very high hurdle of placebo***." 42. Conterno: Conterno further asserted that, based on his review of the data, "***I do not believe that the data warrants a 'Black Box'" warning,*** and while not receiving the warning would require Roxadustat to meet "a pretty high standard," Conterno was "***very excited and delighted with the results that we got . . . out of cardiovascular safety."*** 43. Conterno: Conterno further asserted that based on the only guidance the Company had purportedly received from the FDA, which was for diabetes, ***there was "a 1.3 upper bound" for non-inferiority***, and ***"when we looked at the pooled analysis . . we do basically see hazard ratios, about 1—slightly higher than 1, but the upper bound in each one of these cases, is below 1.3."***	Defendants' *post hoc* manipulations of the Roxadustat data that were designed to make the data appear significantly better and safe than it was. In truth, under the FDA's prespecified analyses, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo and decidedly *inferior to* and caused *more deaths than* Epogen, the current standard of care for which there was already a "Black Box" warning—rendering Roxadustat too dangerous to be approved *at all*, for any patient population. For this reason, Defendants' suggestion that Roxadustat's safety data would not warrant any "Black Box" warning was also materially false and misleading—as Defendants knew, Roxadustat was already *less safe* than Epogen, which itself already had the "Black Box" warning. *Second*, Defendants' claims that Roxadustat had achieved inferiority in the MACE endpoint by referencing the non-inferiority margin of 1.3 was also false. As set forth above, the FDA revealed during the AdCom that it had never agreed with FibroGen on a non-inferiority hazard ratio margin of 1.3—to the contrary, based on prior experience with ESAs the FDA's goal was a non-inferiority margin of 1.25. Moreover, under the FDA prespecified analyses that FibroGen *never disclosed*—and which were in fact disclosed *by the FDA only* during the July 15, 2021 AdCom—Roxadustat's hazard ratio margins were	

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				significantly worse and reached or *exceeded* 1.3 in every key endpoint.	
44	187-188	Speaker(s): FibroGen, Yu (CMO) Date: March 2, 2020 Occasion: 4Q and FY 2019 Earnings Call	44. Yu: Defendant Yu stated that "[R]oxadustat can potentially better address CKD anemia than what is currently available to CKD patients on dialysis and those not on dialysis" due to "***the robust efficacy and safety profile demonstrated***." In particular, Yu referenced the purported ***"lower transfusion risk than [Epogen] patients, while lowering MACE+ risk in the dialysis patient pool"*** and highlighted that the Company was ***"particularly excited about the cardiovascular safety results of the incident dialysis population,"*** which purportedly ***"demonstrated a meaningful reduction in cardiovascular safety risk, as Roxadustat-treated incident dialysis patients had a 30% lower MACE risk and a 34% lower MACE+ than [Epogen]-treated patients.***" Yu further stated that, ***"with respect to cardiovascular safety, Roxadustat was comparable to placebo in risk of MACE and MACE+***" and that "we have designed a program to demonstrate safety in comparison to placebo and with the hope and ***confidence of***	In addition to the reasons for falsity provided in connection with Statements 1-4, 8-13, 14-21, 23-24, 25-27, 29-32, 33-35, and 39-43, Defendant Yu's statements in the 4Q and FY 2019 Earnings Call were materially false and misleading, and omitted material facts when made, for the following additional reasons. *First*, Defendants' claims of Roxadustat's "robust" safety and efficacy data, and that Roxadustat had "demonstrated a meaningful reduction" in MACE and MACE+ risk over Epogen for the incident dialysis population, were plainly false as these statements were based on Defendants' *post hoc* manipulations of the Roxadustat data that were designed to make the drug appear significantly safer than it was. As Defendants admitted on April 26, 2021—and contrary to Defendants' statements above—under the actual prespecified analyses agreed upon with the FDA, "we cannot conclude that Roxadustat reduces the risk of (or is superior to) MACE+ in [DD], and MACE and MACE+ in incident dialysis compared to [Epogen]." *Second*, under the FDA's prespecified sensitivity analyses that Defendants never disclosed during the Class Period, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than (and not at all comparable to) placebo and decidedly *inferior to* and causing *more deaths than* Epogen, the current standard of care for	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13 and 14-21.

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			gaining clean safety label for non-dialysis."	which there was already a "Black Box" warning—rendering Roxadustat too dangerous to be approved *at all*, for any patient population. For this reason, Defendants' suggestion that Roxadustat's safety data would warrant a "clean safety label" for NDD patients was similarly false—as Defendants knew, Roxadustat was already *less safe* than Epogen, which itself already had the "Black Box" warning.	
45	187-188	**Speaker(s)**: FibroGen, Conterno (CEO) and Cotroneo (CFO) **Date**: March 2, 2020 **Occasion**: 2019 Form 10-K	45. Defendants: The Form 10-K reiterated the detailed MACE safety results set forth in the November 8, 2019 and March 2, 2020 press releases.	*See* reasons for falsity provided in connection with Statements 29-32 and 39-44.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13 and 14-21.
46-49	189, 191	**Speaker(s)**: FibroGen, Yu (CMO) **Date**: May 7, 2020 **Occasion**: 1Q 2020 Earnings Call	46. Yu: Regarding Roxadustat safety, Defendant Yu stated that "[i]mportantly, ***we have demonstrated cardiovascular safety in the overall dialysis population and in MACE*** . . . In our 1,530-incident dialysis patient pool, where the comparison between Roxadustat with epoetin alpha started within the first 4 months of dialysis initiation, ***Roxadustat had a 30% lower risk of MACE and 34% lower risk of MACE+ than***	In addition to the reasons for falsity set forth above, Defendant Yu's statements in the 1Q 2020 Earnings Call were materially false and misleading, and omitted material facts when made, for the following additional reasons. Defendants knew that they had not "demonstrated cardiovascular safety" for Roxadustat, that Roxadustat was not comparable to placebo or Epogen, and that it was not statistically superior to Epogen in the incident dialysis population. Indeed, unbeknownst to	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13 and 14-21.

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			epoetin alfa, with a trend towards lower or cause mortality, relative to epoetin alfa." 47. Yu: With respect to DD patients, **Yu stated "looking at safety -- *cardiovascular safety, it does not change any of the conclusions that we have on the -- about Roxadustat being safe and efficacious."*** 48. Yu: With respect to NDD patients, Yu asserted that ***"placebo is the gold standard. With -- in comparison to placebo, we have demonstrated that cardiovascular safety in the MACE endpoint and MACE+ endpoint."*** 49. Yu: Yu stated that, ***"in conclusion, Roxadustat, excellent cardiovascular safety profile***, coupled with the statistically significant and clinically meaningful, higher hemoglobin efficacy results and ***lower transfusion rate relative to epoetin alfa,*** together makes Roxadustat potentially a ***better treatment option*** for dialysis-dependent patients. ***We like the hand that we have and expect the product label to reflect the results of clinical trials*** on our compound."	investors, Defendants' had improperly *post hoc* manipulated the Roxadustat data to make the drug appear significantly better and safer than it was. As Defendants were forced to admit on April 6, 2021—and contrary to Defendants' statements above highlighting the purported statistically significant 30% and 34% reduction in MACE and MACE+ risk in the crucial incident dialysis population—under Roxadustat's undisclosed prespecified analyses, there was no evidence of any purported reduction of MACE risk in this population *at all.* Furthermore, as the FDA would determine during the July 15, 2021 AdCom, under the prespecified sensitivity analyses that Defendants had concealed from investors, Roxadustat was decidedly *inferior* to placebo and Epogen, despite Epogen's "Black Box" warning." Moreover, Defendants knew that Roxadustat's efficacy was also not superior to Epogen. As the FDA would determine, Roxadustat's efficacy benefits compared to existing therapies were, at best, "unclear" and "difficult to calculate," with the FDA stating that the claimed reduction in blood transfusions versus Epogen was inconclusive at best and ***likely nonexistent*** at the untested lower doses that the Company was ultimately forced to propose in order to address significant safety issues.	
50	190-191	**Speaker(s)**:	50. Conterno: "[A]s I think about the differentiation of Roxa, number one, I think you	*See* reasons for falsity provided in connection with Statements 46-49.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in

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		FibroGen, Conterno (CEO) **Date**: May 14, 2020 **Occasion**: Bank of America Securities 2020 Health Care Conference	have to start with efficacy . . . ***We actually had lower transfusions with Roxa than with [Epogen] . . . So that benefit to me, I think, is pretty significant***. Clearly, in the—when we look at the totality of the data, ***I find our overall cardiovascular data pretty compellin***g. And in particular, I think ***we need to highlight the incident dialysis data, whereby we basically show a reduction in risk of MACE events at a time that is critical***. And this is—incident dialysis, basically, covers those patients within the first 4 months of starting dialysis. That is the time when a treatment decision is made when it comes to anemia . . . So that I find also quite meaningful. And clearly the data is highly—it was—***compared to [Epogen], it's highly differentiated based on what we can see."***		connection with Statements 1-4, 8-13 and 14-21. In addition, by this time—the spring of 2020—Defendant Conterno claimed that FibroGen was actively preparing for a potential FDA AdCom, which involved reviewing all of the information in the NDA, including the improper presentation of the Company's *post hoc* analysis in that document that FibroGen would later admit on April 6, 2021 that it had to promptly "clarify" with the agency. ¶¶86-87.
51	192, 194	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: June 2, 2020 **Occasion**: Jefferies 2020 Healthcare Conference	51. Conterno: Regarding whether FibroGen expected a "Black Box" warning, Conterno stated: "[W]hen we look at our data, ***I feel it basically shows that the product is safe because of the safety profile when it comes to CV comparable to placebo*** . . . [I]n [DD], ***when it comes to incident dialysis, we do show an actual significant benefit, well, with a 30% reduction in MAC***E . . . When I put those two reasons together, ***I***	In addition to the reasons for falsity set forth above, Defendant Conterno's statements at the Jefferies 2020 Healthcare Conference were materially false and misleading, and omitted material facts when made, for the following additional reasons. As the FDA would expressly determine, Roxadustat's efficacy benefits compared to existing therapies were, at best, "unclear" and "difficult to calculate," with the FDA stating that the claimed reduction in blood transfusions versus	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21 and 50.

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Defendants False and Misleading Statements and Omissions	Reasons Why Defendants' Statements Were False and Misleading When Made	Facts Giving Rise to a Strong, Cogent and Compelling Inference of Defendants' Scienter
			look at the compelling nature of our data, and I feel that . . . there's no warrant [for a] Black Box . . ."	Epogen Defendant Conterno touted was in fact inconclusive at best and ***likely nonexistent*** at the untested lower doses that the Company was ultimately forced to propose in order to address significant safety issues. Furthermore, Defendant Conterno's statements that Roxadustat was "safe," "comparable to placebo," and had shown a "significant benefit" in incident dialysis patients by lowering the MACE and MACE+ risk by a statistically significant 30% and 34%, respectively, were plainly false, as all of these statements were based on Defendants' *post hoc* manipulations of the Roxadustat data to make it appear significantly better and safer than it was. Indeed, the purported "statistically significant" and "unbelievable" MACE benefit in incident dialysis patients was only present under Defendants' *post hoc* analysis manipulating the safety data to look much better than it was— as Defendants *admitted* on April 6, 2021, under the actual prespecified analyses agreed upon with the FDA, Defendants could not "conclude that Roxadustat reduces the risk of . . . MACE and MACE+ in incident dialysis compared to [Epogen]." Moreover, rather than the Roxadustat data not warranting a "Black Box" warning, in truth, under the FDA's prespecified sensitivity analyses that Defendants never disclosed to investors, Roxadustat's safety signals were so alarming and "serious" that the drug was *inferior to* Epogen, which already carried a "Black Box" warning—rendering	

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				Roxadustat too dangerous to be approved *at all*.	
52	193-194	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: June 4, 2020 **Occasion**: 2020 Annual Shareholder Meeting	52. Conterno: Conterno stressed to investors the importance of the MACE safety results in incident dialysis patients, stating: ***"Importantly, CV safety was demonstrated across all studied populations. Non-dialysis-dependent, incident dialysis and dialysis dependent... In incident dialysis patients, Roxadustat reduced risk of major adverse cardiovascular events or MACE by 30%***. And reduce[d] the risk of MACE+ by 34% compared to [Epogen]. ***Both results were statistically significant . . .*** Roxadustat clearly provides a large clinical benefit in the incident dialysis patient population, and we believe this is a natural decision point for health care professional[s] when selecting which therapeutic agent will be utilized in the treatment of anemia."	*See* reasons for falsity provided in connection with Statements 51.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21 and 50.
53-55	195-197	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: June 9, 2020 **Occasion**: Goldman Sachs 41st	53. Conterno: During the conference, Conterno stated: "I think as you know, I've been very excited about our incident dialysis data and ***the fact that we showed a 30% reduction in MACE risk and 34% when it comes to MACE plus. Honestly, that's huge and that's an anchor***. Because as patients start	In addition to the reasons for falsity set forth above, Defendant Conterno's statements at the Goldman Sachs 41st Annual Global Healthcare Conference were materially false and misleading, and omitted material facts when made, for the following additional reasons. Indeed, the purported "statistically significant" MACE benefit in incident dialysis patients taking Roxadustat was only present under Defendants' *post hoc*	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21 and 50.

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Defendants False and Misleading Statements and Omissions	Reasons Why Defendants' Statements Were False and Misleading When Made	Facts Giving Rise to a Strong, Cogent and Compelling Inference of Defendants' Scienter
		Annual Global Healthcare Conference	dialysis, clearly part of that dialysis initiation is going to be treatment of anemia. And I believe that ***we have the very best data. It's quite compelling and differentiated."*** 54. Conterno: Conterno later reiterated that Roxadustat had ***"showed a significant benefit when it comes to MACE in [the incident dialysis] population, 30% reduction in MACE,"*** which was an ***"unbelievable result"*** and ***"probably the most compelling data that we have."*** 55. Conterno: Conterno further represented that ***"given that [FibroGen] showed [Roxadustat had] basically comparable safety to placebo"—which was "very difficult to achieve"—the Company had "the very best chance basically to have a label without a 'Black Box."***	analysis manipulating the safety data to look much better than it was. As Defendants *admitted* on April 6, 2021, rather than lowering the MACE and MACE+ risk in incident dialysis patients by a statistically significant 30% and 34%, respectively, the actual prespecified analyses agreed upon with the FDA showed the exact opposite, to the point that Defendants were forced to admit that they could not "conclude that Roxadustat reduces the risk of . . . MACE and MACE+ in incident dialysis compared to [Epogen]"—meaning that there was no evidence of any purported reduction of MACE risk in this population *at all.* Moreover, rather than the Roxadustat data not warranting a "Black Box" warning, the exact opposite was true. Under the FDA's prespecified sensitivity analyses that Defendants never disclosed to investors, Roxadustat was decidedly *inferior to* Epogen—rendering Roxadustat too dangerous to be approved *at all*.	
56-57	198, 200	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: August 6, 2020 **Occasion**:	56. Conterno: While Conterno stated that moving forward, there would be no public discussion regarding labeling, he stated "clearly, ***we view that Roxadustat will be successful*** -- I think I've mentioned this to you and others in the past, ***very successful regardless… We continue to view that our data shows a very positive benefit-risk profile for the product."***	In addition to the reasons for falsity set forth above, Defendant Conterno's statements during the 2Q 2020 Earnings Call were materially false and misleading, and omitted material facts when made, for the following additional reasons. Defendants' claim that "Roxadustat will be successful," that FibroGen had "positive" "engagement with the FDA," and that the Company had "positive" MACE results for Roxadustat that	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21 and 50.

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Defendants False and Misleading Statements and Omissions	Reasons Why Defendants' Statements Were False and Misleading When Made	Facts Giving Rise to a Strong, Cogent and Compelling Inference of Defendants' Scienter
		2Q 2020 Earnings Call	57. Conterno: Conterno added, ***"our engagement and our interaction with the FDA was positive. So we feel good about the progress that we are making."***	supported the NDA submission were plainly false because all of these statements were entirely dependent upon Defendants' own *post-hoc* manipulations that completely altered the actual Roxadustat MACE results and made the drug seem much safer than it was. In truth, as the FDA would reveal at the end of the Class Period, under the FDA's prespecified analyses—which Defendants were not "pleased" with and in fact attempted to desperately conceal throughout the Class Period—Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo and decidedly *inferior to* Epogen, the current standard of care for which there was already a "Black Box" warning—rendering Roxadustat too dangerous to be approved *at all*, for any patient population.	
58	199-200	**Speaker(s)**: FibroGen, Conterno (CEO), Cotroneo (CFO) **Date**: August 6, 2020 **Occasion**: 2Q 2020 Form 10-Q	58. Defendants: The 10-Q stated that "***the Company received positive topline results from analyses of pooled MACE and MACE+ data from its Phase 3 trials for Roxadustat, enabling the Company's NDA submission to the FDA***."	*See* reasons for falsity provided in connection with Statements 56-57.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21 and 50.

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59-60	201, 203-204	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: September 9, 2020 **Occasion**: Citigroup 15th Annual BioPharma Conference	59. Conterno: A Citigroup analyst asked how investors should think about Roxadustat in light of its main competitor's negative safety results released the prior week. Specifically, competitor Akebia's anemia drug Vadadustat had failed to show non-inferiority in the NDD group compared to ESAs, with a hazard ratio above 1.25. Conterno responded by reaffirming Roxadustat's MACE results in the NDD population, citing ***"the significant level of evidence that we have already with Roxadustat around NDD,"*** and how the Company was ***"able to show non-inferiority relative to placebo, which is a higher bar than a comparison to a product that had – or product [that has] box warnings. So we feel very good about our pool MACE data in NDD."*** 60. Conterno: Conterno further stated: "I think what I can say is ***we feel very good about where we are in terms of the review with the FDA,*** the level of engagement that we have. I know this question about a [Black Box] warning comes often, which is are going to get one or not . . . But we feel very good about the level of energy that we have. ***I think what I've said before is that we have excellent data. We don't believe that the data that we have***	In addition to the reasons for falsity set forth above, Defendant Conterno's statements during the Citigroup 15th Annual BioPharma Conference were materially false and misleading, and omitted material facts when made, for the following additional reasons. *First*, all of Defendants' statements that the Company had shown Roxadustat was "non-inferior" to placebo, that no Black Box warning would be required, and that conversations with the FDA were going well due to the Company's "excellent" Roxadustat data were false because they were entirely dependent upon Defendants' own *post-hoc* manipulations that completely altered the actual Roxadustat clinical trial results and made the drug seem much better and safer than it was. In reality, Roxadustat was not "comparable to placebo," as under the true, undisclosed prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo *and* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population. *Second*, for this reason, Defendants' statement that Roxadustat's safety data would not warrant any "Black Box" warning was also materially false and misleading—as Defendants knew, under prespecified analyses, Roxadustat was already *less safe* than Epogen, which itself already had the "Black Box" warning. Indeed, as CW 3 would confirm, the FDA concluded as much by no later than the fall of 2020, when it	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21 and 50.

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			warrants a [Black Box] warning."	directly informed Defendants that—at the very least—Roxadustat would most definitely require a "Black Box" warning, if it could be approved at all. *Third*, Defendants knew but failed to reveal in response to the analyst's direct question that, just like Akebia's drug Vadadustat, in NDD patients, Roxadustat had also failed to reach the MACE safety non-inferiority margin the FDA was looking for—which, unbeknownst to investors and as the FDA would reveal during the July 15, 2021 AdCom, was 1.25 and not 1.3. Indeed, as FibroGen would admit on April 6 ,2021, the FDA's prespecified ITT analysis showed a hazard ratio for NDD patients with an upper bound of ***1.27***—and as the FDA would reveal on July 15, 2021, the undisclosed prespecified sensitivity analysis for NDD patients on Roxadustat was even *worse*, as it showed ***an overall hazard ratio of 1.38 with an upper bound reaching 1.7.***	
61	202-204	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: September 16, 2020 **Occasion**: Morgan Stanley 18th Annual Global	61. Conterno: Conterno commenced the conference by touting the MACE data for Roxa, stating "Roxadustat has a very significant data set in NDD . . . ***when we look at MACE, we were non-inferior relative to placebo, which is a higher bar than ESAs would be. So we feel very good about our data there***."	*See* reasons for falsity provided in connection with Statements 59-60.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21 and 50.

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		Healthcare Conference			
62-65	205-206	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: November 5, 2020 **Occasion**: 3Q 2020 Earnings Call	62. Conterno: Conterno stated that the "Roxadustat ***clinical data demonstrated consistent efficacy and reassuring safety results across the continuum of CKD patients with anemia.***" 63. Conterno: Regarding NDD patients, Conterno stated that Roxadustat "has the ***right efficacy safety profile to be able to have a really good uptake in the NDD setting and be able to be a catalyst for the overall expansion of that market."*** 64. Conterno: Further discussing NDD, Conterno told investors that "I think what's important is when – first, when we look at the overall trial, we basically see that in ***NDD, we were comparable to placebo. So that's when it comes to MACE. So that's critically important. We showed non-inferiority."*** 65. Conterno: Regarding incident dialysis patients, Conterno stated, "I think if we think about straight off the bat, in incident dialysis, ***the excellent data that we have with – showing basically reduced cardiovascular outcomes in this population, so that's extremely important."***	In addition to the reasons for falsity set forth above, Defendant Conterno's statements during the November 5, 2020 3Q 2020 Earnings Call were materially false and misleading, and omitted material facts when made, for the following additional reasons. Defendants' statements that Roxadustat's clinical trial data "demonstrated consistent efficacy and reassuring safety" across the tested patient populations, that it was "comparable" to placebo, and that there were "reduced cardiovascular outcomes" in incident dialysis patients were false. In reality, these statements were entirely dependent upon Defendants' own *post-hoc* manipulations that completely altered the actual Roxadustat data and made the drug seem much better and safer than it really was. Indeed, under the true, undisclosed prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo *and* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21 and 50. Additionally, Plaintiffs' CWs gave mutually corroborating accounts that by the fall of 2020—months before Defendants would reveal the truth and at the same time Defendants were assuring investors that Roxadustat safety data did not warrant a "Black Box"—the FDA had already directly informed FibroGen that, at the very least, a "Black Box" warning would be required as the agency had become aware of more and more safety issues with Roxadustat. ¶¶128-32, 240.

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66	207, 209	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: November 17, 2020 **Occasion**: Stifel 2020 Virtual Healthcare Conference	66. Conterno: During the conference, analysts queried whether the fact that the FDA had never called an Advisory Committee—or a committee of external experts the FDA would often call to assist it in evaluating new drugs that may require particular expertise--to review the Roxadustat NDA was a positive sign. In response, Conterno stated: "Given the chance of an AdCom, ***we had to prepare for one but that's really water under the bridge***… at this stage, I think what I can say is basically we have to ***rely on the data that we've shared.*** And I feel that ***the data that we shared,*** I think is ***very compelling when it comes to Roxadustat***…the broad safety data that we have first thing in DD where we look at both our safety data there when we compare to ESAs. As you know ***we had pretty compelling data when it comes to incident dialysis we had statistics in terms of a reduction in the number of MACE events in that setting.*** And then when we look ***at NDD, we were compared to placebo and we basically had comparability when it comes to overall safety***. So, feel very good about the overall package that we had . . . ***Clearly we've already said and have***	In addition to the reasons for falsity set forth above, Defendant Conterno's statements during the Stifel 2020 Virtual Healthcare Conference were materially false and misleading, and omitted material facts when made, for the following additional reasons. Indeed, Defendants had *post hoc* manipulated the Roxadustat data in order to make the drug appear significantly better and safer than it really was. Nor had Roxadustat shown a statistically significant benefit in the incident dialysis population. As Defendants *admitted* on April 6, 2021, rather than lowering the MACE and MACE+ risk in incident dialysis patients by a statistically significant 30% and 34%, respectively, the actual prespecified analyses agreed upon with the FDA showed the exact opposite, to the point that Defendants were forced to admit that they could not "conclude that Roxadustat reduces the risk of . . . MACE and MACE+ in incident dialysis compared to [Epogen]"—meaning that there was no evidence of any purported reduction of MACE risk in this population *at all*. Furthermore, as Defendants were well aware, Roxadustat's cardiovascular safety data did not support FDA approval. Rather, under the true, undisclosed prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "serious" that the drug decidedly *inferior to* placebo *and* Epogen—rendering Roxadustat too dangerous to be approved *at all*. Indeed, as confirmed by	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21, 50 and 62-65.

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			demonstrated both the efficacy and the safety of the product."	Plaintiffs' CWs, by November 2020 the FDA had already informed Defendants that due to numerous safety concerns with Roxadustat, at the very least, a "Black Box" warning would be required for Roxadustat.	
67-69	208-209	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: November 19, 2020 **Occasion**: Jefferies Virtual London Healthcare Conference	67. Conterno: As in the conference two days before, Conterno told investors: "***Clearly, we have a high level of conviction on the overall submission, the strength of our data***…" 68. Conterno: Conterno reiterated, "Clearly, I think the -- ***when we look at our data, we continue to feel that the data basically offers a very favorable risk-benefit profile for patients across the continuum***." "[W]here ESAs are really not working very well." 69. Conterno: Conterno stated that "Roxadustat will be an excellent option there, okay? ***What about the incident dialysis population, where we basically showed a very significant benefit when it comes to MACE and MACE+."***	*See* reasons for falsity provided in connection with Statement 66.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21, 50 and 62-65.
70-71	211-215	**Speaker(s)**: FibroGen, Frost (Senior VP)	70. Defendants: Frost stated, "***Cardiovascular safety of Roxadustat was also carefully evaluated, and demonstrated in the Phase 3 program,*** by assessment of major adverse cardiovascular events (MACE) from pooled analyses of Phase 3	In addition to the reasons for falsity set forth above, Defendant FibroGen and Senior VP Frost's statements in the December 9, 2020 Letter to the FDA Responding to the Citizen Petition were materially false and misleading, and omitted material facts when made, for the following additional reasons.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21, 50 and 62-65.

		Date: December 9, 2020 **Occasion**: Letter to the FDA Responding to the Citizen Petition	studies. In the MACE analysis of the DD-CKD patient pool, "***[R]oxadustat demonstrated non-inferiority compared to epoetin-alfa, and in the NDD-CKD pool, Roxadustat demonstrated non-inferiority to placebo with respect to MACE.***" 71. Defendants: Regarding the NDA submission, the letter added: ***"FibroGen's NDA submission was complete, complied with all FDA guidance, and included data from all clinical and preclinical studies.*** The Integrated Summary of Safety cardiovascular safety report includes the pooled cardiovascular safety analyses of the DD-CKD, and NDD-CKD patient populations. In addition, for completeness and full transparency, FibroGen included certain cardiovascular safety sensitivity analyses, including the stable dialysis subgroup, and the DD-CKD pool including the PYRENEES study. ***The results from these sensitivity analyses do not change the conclusions with respect to MACE of non-inferiority of roxadustat to epoetin-alfa in DD-CKD patients, and non-inferiority of roxadustat to placebo in NDD-CKD patients. In conclusion, FibroGen's NDA submission was complete and transparent. The data supporting the safety and effectiveness of roxadustat is robust and compelling."***	*First*, Defendants' statements in response to the Citizen Petition that the "cardiovascular safety" of Roxadustat was "demonstrated in the Phase 3 program," and that Roxadustat had demonstrated "non-inferiority" compared to Epogen and placebo in the Phase 3 trials, were plainly false. In reality, Defendants had made *post hoc* manipulations to the Roxadustat data in order to make it appear significantly better and safer than it was. *Second*, the data was not based on any prespecified analyses agreed upon with the FDA. Rather, under the FDA's prespecified analyses, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo *and* Epogen, which already carried a "Black Box" warning. Indeed, as confirmed by Plaintiffs' CWs, by the fall of 2020 the FDA had already informed Defendants that, at the very least, a "Black Box" warning would be required for Roxadustat due to the FDA's growing safety concerns. *Third*, as Defendants would themselves soon admit, FibroGen's NDA submission to the FDA was *not* "complete and transparent"—to the contrary, and as the Company admitted in the April 6, 2021 press release, the Company had misleadingly submitted much more favorable manipulated *post hoc* safety analyses in the NDA as the primary safety analyses, forcing the Company to have to rush to "clarify" what post hoc changes were made to the FDA. *Fourth*, while the Company claimed in its response to the Citizen Petition that "sensitivity analyses" did not change any conclusion that the MACE risk of	

Stat. #(s)	CC ¶¶'s	Speaker, Date, and Occasion	Defendants False and Misleading Statements and Omissions	Reasons Why Defendants' Statements Were False and Misleading When Made	Facts Giving Rise to a Strong, Cogent and Compelling Inference of Defendants' Scienter
				Roxadustat was non-inferior to placebo or Epogen, in truth, the FDA's prespecified sensitivity analyses—which Defendants wholly concealed from investors throughout the Class Period--revealed highly alarming safety results for Roxadustat showing that Roxadustat was inferior to placebo *and* Epogen, despite its Black Box warning.	
72	217, 220	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: March 1, 2021 **Occasion**: Press release announcing that the FDA would hold an AdCom meeting	72. FibroGen and Conterno: While FibroGen stated it was "disappointed" with the news, Defendant Conterno was quoted as stating: ***"We continue to be confident in the efficacy and safety profile of [Roxadustat] based on positive results from a global Phase 3 program encompassing more than 8,000 patients."***	In addition to the reasons for falsity set forth above, Defendants' statements in the March 1, 2021 Press Release were materially false and misleading, and omitted material facts when made, for the following additional reasons. *First*, contrary to Defendants' statements about their unwavering "confidence" in the Roxadustat data, as Defendants were well aware, Roxadustat's cardiovascular safety data did not support FDA approval. Rather, Defendants had made significant *post hoc* manipulations to the Roxadustat data in order to make the drug appear much better and safer than it was, and the manipulated data that they presented to the public were not based on any prespecified analyses that had been agreed upon with the FDA. In reality, under the true, undisclosed prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "serious" that the drug was too dangerous to be approved *at all*, for any patient population. *Second*, as Defendants would themselves admit only one month later, FibroGen's NDA submission to the FDA was *not* "complete"—to the contrary, and as the Company would soon admit on April 6,	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21, 50 and 62-65.

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				2021, FibroGen had misleadingly submitted its manipulated *post hoc* safety analyses in the NDA to the FDA as the primary analyses, forcing the Company to immediately "clarify" the issue with the FDA.	
73-74	218, 220	**Speaker(s)**: FibroGen, Conterno (CEO), Eisner (CMO) **Date**: March 1, 2021 **Occasion**: 4Q and FY 2020 Earnings Call	73. Eisner: Eisner stated: "***We continue to have confidence in the completeness of our NDA submission, the strength of our data***," later adding that "we're very willing and able to have this discussion in public and present our data, which, as we alluded to before, ***we're quite confident in."*** 74. Conterno: Conterno added: ***"[T]he data that we have on incident dialysis, we believe, is some of our strongest data. As we think about MACE and MACE+ significance in that population. So clearly, very, very important data***."	*See* reasons for falsity provided in connection with Statement 72.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21, 50 and 62-65. In addition, in his role as CMO, Defendant Eisner oversees all global clinical development and regulatory affairs for FibroGen. Notably, while Eisner only joined the Company in December 2020, his total compensation for 2020 was substantial, amounting to over $3.5 million. ¶138.
75-78	219-220	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: March 2, 2021 **Occasion**: 41st Annual Cowen Healthcare Conference	75. Conterno: Conterno assured investors that there was no concern despite the previous day's news regarding the AdCom meeting, stating that: "We continue to have confidence in ***the completeness of the NDA submission and the strength of the roxadustat data.***" 76. Conterno: Conterno called the AdCom "an opportunity to basically showcase, I think, the ***strength of our data***, and we continue to have ***confidence on***	*See* reasons for falsity provided in connection with Statement 73-74.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21, 50 and 62-65.

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			the strength of the data of Roxadustat across both DD and NDD." 77. Conterno: Conterno further asserted that the totality of the data for DD and NDD patients "***supports -- the benefit risk profile***." 78. Conterno: Conterno added that "I know because we've discussed in the past, and I think ***I've been pretty clear in terms of what has been agreed with the FDA and what hasn't been agreed with FDA. I think that's known***."		
79-81	222, 227-229	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: April 6, 2021 **Occasion**: Press release announcing that the primary cardiovascular safety analyses included post-hoc changes to the	79. Conterno: Conterno was quoted in the press release as stating that ***"this does not impact our conclusion regarding the comparability, with respect to cardiovascular safety, of Roxadustat to [Epogen] in dialysis-dependent (DD) patients and to placebo in non-dialysis dependent (NDD) patients."*** 80. Conterno: "***We continue to have confidence in Roxadustat's benefit risk profile***." 81. Press Release: The press release reiterated that "[t]hese analyses do not change the Company's assessment that ***Roxadustat is comparable to placebo in non-dialysis dependent patients and to***	In addition to the reasons for falsity set forth above, Defendants' statements in the April 6, 2021 Press Release were materially false and misleading, and omitted material facts when made, for the following additional reasons. Specifically, Defendants knew that Roxadustat was not comparable to placebo or Epogen, nor did it have a "favorable" risk-benefit profile. Rather, in truth, while Defendants purported to come clean on April 6, 2021 by releasing data showing the real hazard ratios under the FDA's prespecified *primary* analyses, Defendants *still* did not disclose the FDA's prespecified and equally important *sensitivity* analyses—*i.e.*, analyses that were indisputably a key part of the "totality" of the data—which Defendants had wholly withheld from investors throughout the Class Period.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21, 50 and 62-65. In addition, the fact that Defendants did not themselves reveal the full truth about the highly negative safety profile for Roxadustat that doomed its approval prospects—such that it was revealed by the FDA only during the July 15, 2021 AdCom—strongly supports an inference of scienter. ¶¶244, 249.

		stratification factors.	***[Epogen] in dialysis dependent patients using MACE to measure cardiovascular safety***."	These critical sensitivity analyses made clear that Roxadustat was significantly inferior to placebo *and* Epogen in the MACE *and* ACM endpoints in numerous and alarming ways. Indeed, based on the data from the FDA's prespecified sensitivity analyses, the FDA AdCom would conclude that "there were greater rates of some important adverse events with Roxadustat than even [Epogen]"—including deaths—and that Roxadustat could "not match the efficacy of [Epogen]" even if the Roxadustat dose were lowered to potentially lessen the safety issues. As a result of these "serious" safety concerns, the FDA AdCom would vote overwhelmingly *against* the approval of Roxadustat for *any* patient population, and even with a Black Box warning. Additionally, as the chart in ¶228 demonstrates, the FDA expressly noted the "considerable difference" between the results in the crucial MACE and ACM endpoints as between (i) FibroGen's *post hoc* manipulated analysis; (ii) the primary prespecified FDA analysis Defendants belatedly revealed on April 6, 2021; and (iii) the prespecified FDA sensitivity analyses Defendants ***never revealed***. Significantly, for NDD patients, under the undisclosed FDA prespecified sensitivity analyses the estimated MACE hazard ratio was ***1.38***, or nearly ***30% higher*** than the estimated MACE hazard ratio of 1.08 Defendants had originally disclosed pursuant to the doctored *post hoc* analysis—and the upper bound for that endpoint was higher still, at ***1.7, or nearly 40% higher*** than the upper bound of 1.24 Defendants had originally disclosed.	

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				The same was true for the ACM endpoint in the NDD patient population, for which the FDA's sensitivity analysis showed an estimated hazard ratio of ***1.4, or over 30% higher*** than the estimated hazard ratio Defendants originally disclosed of 1.06, with the upper bound for that endpoint reaching as high as ***1.82—or 48% higher*** than the upper bound of 1.23 Defendants had disclosed pursuant to the manipulated *post hoc* analysis. The prespecified sensitivity results for the DD population also showed a significant difference, as the upper bound for the MACE endpoint was ***1.3, or over 15% higher*** than the upper bound of 1.13 Defendants originally disclosed—and for the ACM endpoint, the prespecified sensitivity analysis showed an upper bound of ***1.35, which was also over 15% higher*** than the upper bound of 1.17 Defendants had presented under the manipulated *post hoc* analysis.	
82-89	223-229	**Speaker(s)**: FibroGen, Conterno (CEO), Eisner (CMO) **Date**: April 6, 2021 **Occasion**: "Business Update Call" to	82. Conterno: During the call, Conterno falsely attempted to assuage concerns regarding the cardiovascular safety of Roxadustat: "Our conclusion regarding ***the comparability with respect to cardiovascular safety of Roxadustat to [Epogen] in dialysis-dependent patients and to placebo in nondialysis-dependent patients is not impacted***. So let me be very clear. We continue to have ***confidence in Roxadustat's***	In addition to the reasons for falsity set forth above, Defendants' statements during the April 6, 2021 Business Update Call were materially false and misleading, and omitted material facts when made, for the following additional reasons. Defendant Conterno's statement that FibroGen had no agreement with the FDA on whether the upper bound for the non-inferiority margin should be 1.3 or 1.25 was materially false because Conterno concealed the critical fact—as the FDA would reveal during the July 15, 2021 AdCom—that the reason for the lack of agreement was that the FDA had	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21, 50, 62-65 and 79-81.

		Discuss Admissions	***benefit risk profile, and we're committed to working closely with the FDA to bring this important new treatment to patients living with anemia of CKD."*** 83. Eisner: Eisner stressed that "these analyses do not change the Company's assessment that ***Roxadustat is comparable to placebo in nondialysis-dependent patients and to [Epogen] in dialysis-dependent patients using MACE to measure cardiovascular safety***." 84. Conterno: In response to another analyst inquiry regarding whether the upper bound of the confidence intervals that was pre-agreed with the FDA was 1.25 or 1.3 for noninferiority, Conterno stated that ***"in non-dialysis, we basically show comparability relative to placebo***. With regards to the 1 point to any measures of excess risk***, you mentioned 1.25 or 1.3, I think I said in a number of different occasions that we do not have a pre-agreed non-inferiority margin with the FDA."*** 85. Conterno: "But clearly, ***our conclusions when it comes, as I mentioned, to -- in NDD and DD that we're comparable to placebo in NDD and comparable in DD to EPO have not changed a from a safety perspective***. I think that's a ***critically important message.*** When it comes to incident	stated all along that an upper bound of ***1.25*** (and ***not*** 1.3) was what it was looking for. Indeed, the FDA stated that it had explicitly *rejected* the Company's proposal of 1.3 as the upper bound because FibroGen had attempted to choose that non-inferiority margin for itself, *post hoc*, *i.e.*, after the results of the Roxadustat safety data were fully known to FibroGen. As a result, the true upper bound hazard ratios for the Roxadustat safety data under the FDA's prespecified sensitivity analyses Defendants never disclosed far exceeded the upper bound of 1.25 the FDA was focused on in the key MACE and ACM endpoints across both patient populations, in addition to also reaching or exceeding the 1.3 non-inferiority margin Defendants claimed the FDA wanted to see and that Roxadustat had purportedly cleared. Moreover, for NDD patients, even under the FDA's slightly more favorable *primary* prespecified analysis Defendants belatedly revealed on April 6, 2021, the MACE and ACM hazard ratios still exceeded 1.25—as they were at 1.27 and 1.26, respectively—thus failing the actual non-inferiority margin the FDA was using, but that Defendants concealed from investors throughout the Class Period.	

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			dialysis, the ***numbers continue to be quite positive***." 86. Eisner: "the ***overall analysis are consistent with comparable safety to placebo in the NDD population and to ESA in the dialysis-dependent population.*** And overall, we feel ***very good about the overall benefit-risk profile of the drug."*** 87. Eisner: Further, in response to analyst inquiry regarding Roxa's safety profile, Eisner reiterated that "still, ***the overall results are very comparable in the NDD population to -- for Roxadustat to placebo and in the DD and the incident dialysis subpopulation, comparable to ESA's in terms of cardiovascular safety.*** So overall, we continue to believe that ***the benefit risk profile of Roxadustat is favorable***." 88. Eisner: Eisner again stressed that they could "clearly state that ***the results with the prespecified stratification factors continue to support comparable cardiovascular safety between [R]oxadustat and placebo and a positive benefit risk profile***." 89. Eisner: Eisner concluded that "[a]t the end of the day, we do believe that ***the benefit/risk profile of roxadustat is positive and that the review will likely conclude that***."		

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90-91	230, 232	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: May 10, 2021 **Occasion**: Q1 2021 Earnings Call	90. Conterno: During the call, Conterno stated that the *post hoc* update the Company had provided on April 6, 2021 "***does not impact our overall conclusions regarding the comparability with respect to cardiovascular safety of Roxadustat to [Epogen] in [DD] patients and to placebo in [NDD] patients***." 91. Conterno: Conterno stressed that he "want[ed] to reiterate that we continue to have ***confidence in the Roxadustat data and in the safety and efficacy profile demonstrated in the Phase 3 program."***	In addition to the reasons for falsity set forth above, Defendant Conterno's statements during the May 10, 2021 Q1 2021 Earnings Call were materially false and misleading, and omitted material facts when made, for the following additional reasons. *First*, under the true prespecified analyses required by the FDA, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo and decidedly *inferior to* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population. *Second,* while Defendants purported to come clean by releasing data showing the real hazard ratios under the FDA's prespecified *primary* analyses on April 6, 2021, significantly, Defendants still had not disclosed the FDA's prespecified and equally important *sensitivity* analyses—*i.e.*, indisputably a key part of the "totality" of the data—which unequivocally confirmed that, contrary to Defendants' public statements, Roxadustat was significantly inferior to placebo *and* Epogen in the MACE *and* all-cause mortality endpoints.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21, 50, 62-65 and 79-81.
92-93	231-232	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: May 13, 2021	92. Conterno: During the conference, Conterno stressed that Roxadustat was ***"comparable on both dialysis dependent and non-dialysis dependent comparable to ESAs on dialysis dependent onto placebo on non-dialysis dependent***" and "***can be an ideal choice there given the strength***	*See* reasons for falsity provided in connection with Statement 90-91.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21, 50, 62-65 and 79-81.

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		Occasion: Bank of America Annual Healthcare Conference	***of our data, in particular in incident dialysis***." 93. Conterno: Conterno assured investors that he was "***quite confident on what Roxadustat can deliver***," and added that for Roxa, ***"when it comes to MACE non-inferior to ESAs on DD and non-inferior comparable to placebo on NDD***. . . all in all, I think it should help understand I think the overall profile of the product better, and I'm optimistic about ***given our preparation that we will have a good showing."***		
94-95	233, 235	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: June 4, 2021 **Occasion**: Jefferies Healthcare Conference	94. Conterno: Conterno stated that it was "important [to] highlight" "***that Roxadustat has shown comparability when it comes to both placebo in NDD and relative to EPO in DD***." 95. Conterno: Conterno further claimed that the hazard ratio estimate for DD patients was "***still below 1 and it looks very, very positive***."	In addition to the reasons for falsity set forth above, Defendant Conterno's statements during the June 4, 2021 Jefferies Healthcare Conference were materially false and misleading, and omitted material facts when made, for the following additional reasons. Roxadustat's MACE safety results were in fact not comparable to placebo or Epogen. Rather, in reality, under the FDA's prespecified analyses, Roxadustat's safety signals were so alarming and "serious" that the drug was much more dangerous than placebo *and* Epogen—rendering Roxadustat too dangerous to be approved *at all*, for any patient population. Indeed, Defendants knew that they had still not disclosed the FDA's prespecified and equally important *sensitivity* analyses showing that, contrary to their public statements, Roxadustat was significantly inferior to placebo *and* Epogen in the	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21, 50, 62-65 and 79-81.

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				MACE *and* all-cause mortality endpoints, in addition to causing a host of other undisclosed risks and side effects. Moreover, contrary to Defendant Conterno's assertion that the estimated hazard ratio for DD patients was less than 1, under the FDA's undisclosed prespecified sensitivity analyses in that population, the estimated hazard ratios for MACE and ACM—in addition to having upper bounds of 1.3 and above—exceeded 1 by notable margins (1.14 and 1.17, respectively).	
96	234-235	**Speaker(s)**: FibroGen, Conterno (CEO) **Date**: June 10, 2021 **Occasion**: Goldman Sachs 42nd Annual Global Healthcare Conference	96. Conterno: In response to analyst inquiry regarding the safety of the updated Roxadustat data, Conterno stated that "what the data shows is -- what the analogy shows is basically the ***Roxadustat is comparable to ESAs to EPO in the DD setting and comparable to placebo in the NDD setting***…"	*See* reasons for falsity provided in connection with Statement 94-95.	*See* facts giving rise to a strong, cogent and compelling inference of Defendants' scienter provided in connection with Statements 1-4, 8-13, 14-21, 50, 62-65 and 79-81.